

REMARKS

Claims 9, and 12-14 have been amended herein. Claims 9 and 12-14 remain pending in the Application. No new matter has been added. Entry of the amendment is respectfully requested. Reconsideration is respectfully requested.

Claim 9 was amended to correct a typographical error.

Claims 12-14 were amended as suggested in the Action to refer to “The mammalian NSO cell line” in their preambles.

These amendments merely make the claims more clear and do not change the scope of the claims.

Claim Rejections

Claims 9 and 12-14 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claims 9, 12 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Keen, et al. (*Cytotechnology*, 1996) (“Keen”).

Claims 9 and 12-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Keen in view of Crombet-Ramos, et al. (*Int. J. Cancer*, 2002, published online 27 August 2002).

These rejections are respectfully traversed.

35 U.S.C. § 112, second paragraph rejections

Applicants respectfully submit that one of ordinary skill in the art at the time of the invention would consider the subject matter of claims 9 and 12-14 as being clear and definite in view of the Specification. For example, one of ordinary skill in the art at the time of the invention would consider the recited further supplements to correspond to additions to the growth medium such as proteins, growth factors, lipids, and cholesterol. Withdrawal of the 35 U.S.C. § 112, second paragraph rejection is respectfully requested.

In addition, in order to advance prosecution of the Application, Applicants would be willing to further amend claim 1 to gain allowance of the application. Applicants believe the claims are sufficiently clear and definite to satisfy the statutory mandate. However, Applicants would be willing to consider any suggestions by the Examiner to make the claims even more clear.

35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) rejections

Applicants agree with the Examiner that the present claims correspond to “product-by-process” claims. However, the previous case law regarding such claims (e.g., *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985) has been superceded by *Abbott Labs v. Sandoz, Inc.*, 566 F.3d 1282, 90 USPQ2d 1769 (Fed. Cir. 2009), in which “Process terms in product-by-process claims serve as limitations in determining infringement.” Thus under *Abbott Labs*, method steps in product-by-process claims now directly limit the scope of the claims with respect to determining patentability of the claims. It follows that in order to establish anticipation and/or *prima facie* obviousness, the U.S. Patent Office must now establish that all of the method steps

recited in the pending claims are disclosed or suggested by the applied art. As all of the claims were rejected under the old case-law, Applicants respectfully submit that the rejections are no longer valid and should be withdrawn.

For example, the pending rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) do not establish on the record where steps (I), (II), and (i) to (ix) are disclosed in the applied art. Further, Applicants respectfully submit that these recited steps are not disclosed or suggested in the applied art and one of ordinary skill in the art at the time of the invention would have no apparent reason, or any other rationale for modifying the applied art to carry out these recited steps.

In addition, Applicants respectfully submit that nowhere does Keen (or the other applied art) disclose or suggest how to adapt NSO cells to grow in growth media that is free of further supplements such as cholesterol, its precursors or any lipid source. The claimed cell line is adapted for growth in growth medium that is protein-free, serum-free and free from further supplements such as cholesterol and lipids. PFHM-II from Gibco is an example of such a growth medium disclosed in the specification (e.g. page 8, lines 5-6).

On the other hand, the cell line disclosed by Keen requires supplementation with insulin, cholesterol and/or lipids. The presently claimed cell line grows in a protein and serum free medium completely without such supplements.

Thus Keen does not disclose each and every feature, relationship and step of the claimed invention arranged in the manner recited in the claims, as is required to sustain the rejection. Hence, Applicants' claim 9 patentably distinguishes over Keen. Therefore, it is respectfully

submitted that the 35 U.S.C. § 102(b) rejection over Keen of claim 9 as well as claims 12-13 which depend therefrom, should be withdrawn.

In addition, Applicants respectfully submit that Crombet-Ramos also does not disclose or suggest these recited features that are missing from Keen. Further, Applicants respectfully submit that one of ordinary skill in the art at the time of the invention would not regard claim 9 as obvious in view of a combination of the applied art. The applied art does not disclose or suggest any apparent reason or other rationale to modify the applied art to correspond to the subject matter recited in claim 9.

Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejections of claims 9 and 12-14 should be withdrawn.

Conclusion

Each of Applicants' pending claims specifically recites features and relationships that are neither disclosed nor suggested in any of the applied art. Furthermore, the applied art is devoid of any apparent reason for combining features of the applied art so as to produce Applicants' invention. Allowance of all of Applicants' pending claims is therefore respectfully requested.

The undersigned will be happy to discuss any aspect of the Application by telephone at the Examiner's convenience.

Respectfully submitted,

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